enteric coating (Col. 11, lines 54-55). The enteric coating of the capsules consists of an acrylate, cellulose acetate (Col. 5, lines 5-12). The enteric coating serves to delay active substance release until the composition reaches the intestines (Col. 5, lines 10-12).

Horrobin is silent to the problem of peroxidation of the PUFAs in orally administrable capsules. As the Examiner has acknowledged, a xylose-hardened gelatine capsule is not disclosed in Horrobin.

Acharya (US 5,686,094) discloses that simple or complex carbohydrates such as xylose may be employed to modify a **hydrogel structure** (Col. 5, line 64). The dissolution of the hydrogel complex is effected in this way (Col. 6, lines 1-20). For orally administered chewable products **duration** of release can be adapted by modification of the hydrogel structure.

Xylose coating to gelatine capsules is not disclosed. Acharya is silent to the problem of peroxidation of PUFA.

Morozov et al. (US 5,728,680) discloses in Col. 27, lines 21-57 a parenteral administration of a pharmaceutical composition. The pharmaceutical carrier for the parenteral administration are aqueous solutions. Shelf life stability of these products is improved by adding excipients such as sugars, e.g. xylose (Col. 27, lines 43-46).

Morozov et al. are silent to orally administrable forms of PUFA and their peroxidation.

Argument

Claim 1 has been amended from perilla oil to Polyunsaturated fatty acids (PUFAs). Claim 1 has been amended to recite that the gelatine capsule is xylose-hardened in

order to slow peroxidation of the PUFA. The retarded release time has been moved from claim 1 to claim 3. Claims 1-5 are now believed to distinguish over the combinations of 1) Horrobin and Acharya and 2) Horrobin, Acharya and Morozov, as discussed further below.

For gelatine capsules according to Horrobin the person skilled in the art would be confronted with the problem of peroxidation of the PUPA. According to our analysis gelatine capsules which contain PUFAs show increasing peroxidation values already in the first month. The increased number of peroxides in the gelatine capsule makes their use impossible since most of the organic peroxides cause the development of cancerogenic radicals. Furthermore, peroxides irritate, and cauterize skin and mucous membranes as well as the respiratory tracts. In other words, the person skilled in the art has to find a solution to the problem that the peroxidation values of the PUFAs contained in a gelatine capsule rise in the first 12 months to the value of 3, and after 36 months to the value of 11.

In this situation Horrobin gives for the person skilled in the art no suggestion to provide the gelatine capsule with a coating in order to slow down the peroxidation of the PUFA. Horrobin in Col. 11, lines 36-44 seems to suggest adding antioxidants to the PUFA **and not to prepare the gelatine capsule according to the invention**.

Also Acharya does not suggest preparing a gelatine capsule according to the invention. Acharya deals with a controlled duration of release, This problem, however, is not a problem when using gelatine capsules. Furthermore Acharya does not suggest a xylose coating to the gelatine capsule. In the office action it was argued that the combination of Horrobin and Acharya teaches using xylose to control release rates of gelatine capsules. **However, the subject**

matter of the invention is not that xylose hardening may be used to control release rates but rather that xylose hardening of gelatine capsules provides protection against peroxidation of the PUFA.

Even in the light of Morozov et al. the use of xylose as a coating on gelatine capsules is not rendered obvious. As already mentioned above, Morozov et al, only discuss the addition of sugars in the context of aqueous compositions. The whole context deals with parenteral administration which is directly opposed to orally administrable farms. Furthermore, it should be noted that the underlying mechanisms for shelf life stability of aqueous carriers are completely different from those of gelatine capsules. Aqueous carriers are stabilized and usually prepared under aseptic conditions. The pH value is adjusted and excipients axe added to increase the shelf life and pharmacokinetic half-life of the aqueous composition. In sharp contrast to this, gelatine capsules have been filled with antioxidants in order to increase shelf life stability of the product. According to the invention it became possible to increase this shelf life stability by coating the gelatine capsule with xylose. In sharp contrast to Morozov et al. the xylose is not added to the PUFA but rather provided as coating on the gelatine capsule. Morozov et al, does not suggest using xylose-hardened gelatine capsules according to claim 1.

The Use claims 6-10, which were written in international method claim format as claims 7-11, with claim 11 being a new independent claim, and claims 7-10 depending ultimately from new claim 11. Claims 7-11 are believed to be fully supported by the specification as filed.

Applicant believes that amended claim 1-11 are patentable over the cited art and respectfully requests that claims 1-11 be allowed.

Although it was not believed necessary at this time to file a declaration under 37 CFR 1.132, applicant would like to make the Examiner aware of some recent test results. It was found that the 36 month peroxide data show that the xylose-hardened capsules result in a perilla oil PO value of 4, compared to a value of 11 for the non xylose-hardened capsules. This means that after 36 months the quality of the xylose-hardened capsules were still in good condition, but the non xylose-hardened capsules were not in acceptable condition.

If the Examiner believes that this evidence would be useful to the examination, applicant would like the opportunity to submit it in proper declaration form. Although, as stated above, it was not believed to be necessary at this time since the cited combinations fail to meet the claims, as presently amended.

Respectfully submitted,

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Marked Up Claims

The following are marked up versions of amended claims 1-10:

1. (Amended Once) An oral dosage form for food, food supplements and dietetics comprising ~~perilla oil~~ **polyunsaturated fatty acids** in a ~~xylose-hardened~~ gelatine capsule ~~with a retarded release time~~ **which is xylose-hardened in order to slow down peroxidation of the polyunsaturated fatty acids**.

2. (Amended Once) The dosage ~~from~~ **form** as recited in claim 1 comprising omega-3 polyunsaturated fatty acids with a high content of alpha linolenic acid.

3. (Amended Once) The dosage form as recited in claim 1, wherein said **gelatine capsule has a** retarded release time ~~is~~ **of** more than 45 minutes.

4. (Amended Once) The dosage form according to claim 1, wherein said dosage form is operative against diseases of metabolism of fat and/or against intestinal inflammations~~, such as Morbus Crohn and/or colitis ulcerosa~~.

5. (Amended Once) The dosage form according to claim 1, wherein the gelatine capsule comprises ~~an~~ **one** ingredient selected from the group consisting of fish oil, linseed oil and gamma linolenic acid.

6. (Amended Once) ~~Use of a xylose-hardened gelatine capsule in order to prevent peroxidation of a polyunsaturated fatty acid contained in said gelatine capsule, wherein said gelatine capsule has a retarded release time and is used as oral dosage form for food, food supplements and dietetics~~
The dosage form according to claim 1, wherein no antioxidants are added to the polyunsaturated fatty acids.

7. (Amended Once) The ~~use~~ **method** as recited in claim ~~6~~ **11**, wherein said gelatine capsule comprises polyunsaturated fatty acids with a high content of alpha linolenic acid.

8. (Amended Once) The ~~use~~ **method** as recited in claim 7, wherein said gelatine capsule comprises perilla oil.

9. (Amended Once) The ~~use~~ **method** according to claim ~~6~~ **11**, wherein said **gelatine capsule has a** retarded release time ~~is~~ **of** more than 45 min.

10. (Amended Once) The ~~use~~ **method** according to claim ~~6~~ **11**, wherein said gelatine capsule

comprises an ingredient selected from the group consisting of fish oil, linseed oil and gamma linolenic acid.

The following is new claim 11:

11. (New Claim) **A method for slowing down peroxidation of polyunsaturated fatty acids used for food, food supplement and dietetics comprising the step of utilizing a gelatine capsule which is xylose-hardened as oral dosage form for the polyunsaturated fatty acids.**